

Anthem[®]

Patient Reported Outcomes: Health Plan Formulary Decision-Maker Perspective

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Outline

Anthem P&T process overview

Common study limitations

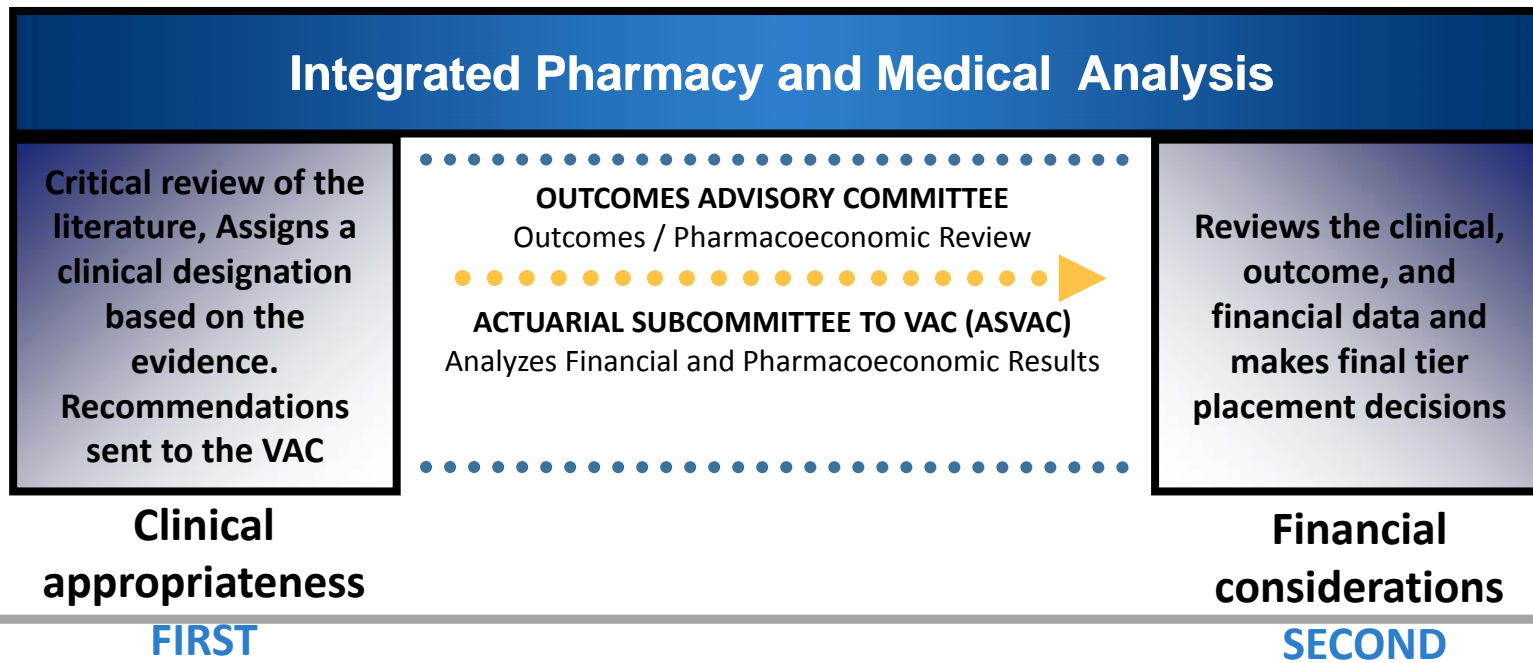
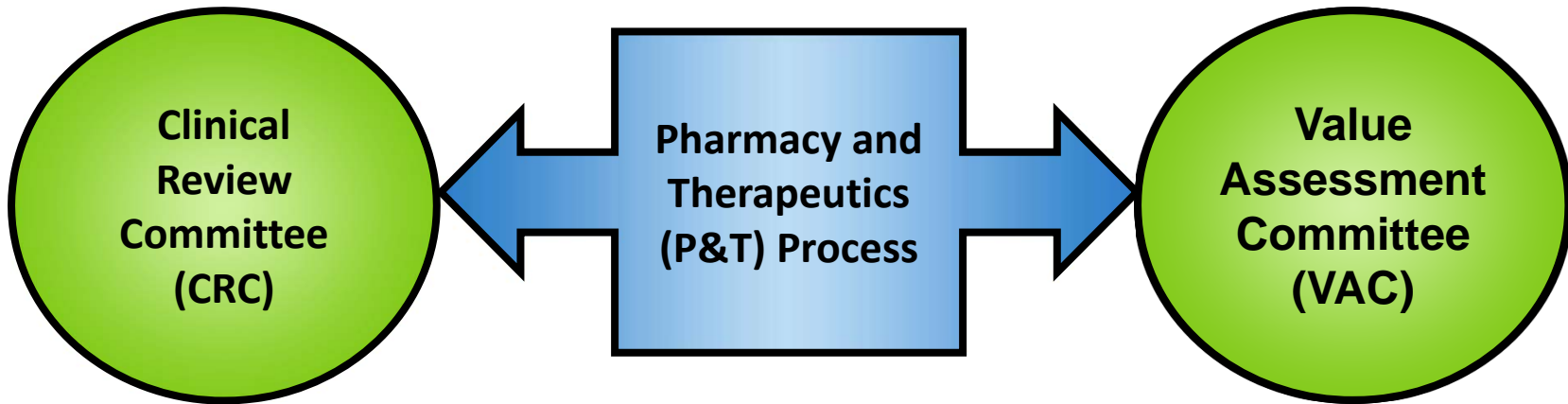
Case example of QoL measurement

- SF-36 (general instrument)
- IBDQ (disease-specific instrument)

Drug pipeline - future opportunity for PROs

Summary

The Anthem Pharmacy and Therapeutics Process



The Anthem Pharmacy and Therapeutics Process: Goal

Improve Health Outcomes

Consider the complete burden of disease

Clinical Burden

Epidemiology

Natural History of Disease

Total Cost of Care

Productivity Impact

Quality of Life Impact

Leverage the formulary process to improve patient outcomes

Improve Quality of Care
(clinical status, quality of life)

Reduce Total Cost
(pharmacy, medical, ancillary, home health, nursing home, etc.)

Optimize Care
(cost effectiveness)

Improve Productivity

Evidence-Based Medicine: Common Study Limitations

High-drop out rates or missing data, with no sensitivity analysis

Use of post-hoc analysis to draw cause and effect conclusions

- Subgroup analysis where subgroups were not determined in advance.

Non-significant findings / power calculation is not clear

Non-ITT analysis (>5% of patients excluded from the primary outcome analysis)

Inadequate dosages, either study drug or comparator

Use of non-validated scoring methods

Disease oriented outcomes only (BP lowering vs. CV mortality)

Meta-analysis with unclear quality assessment methods.

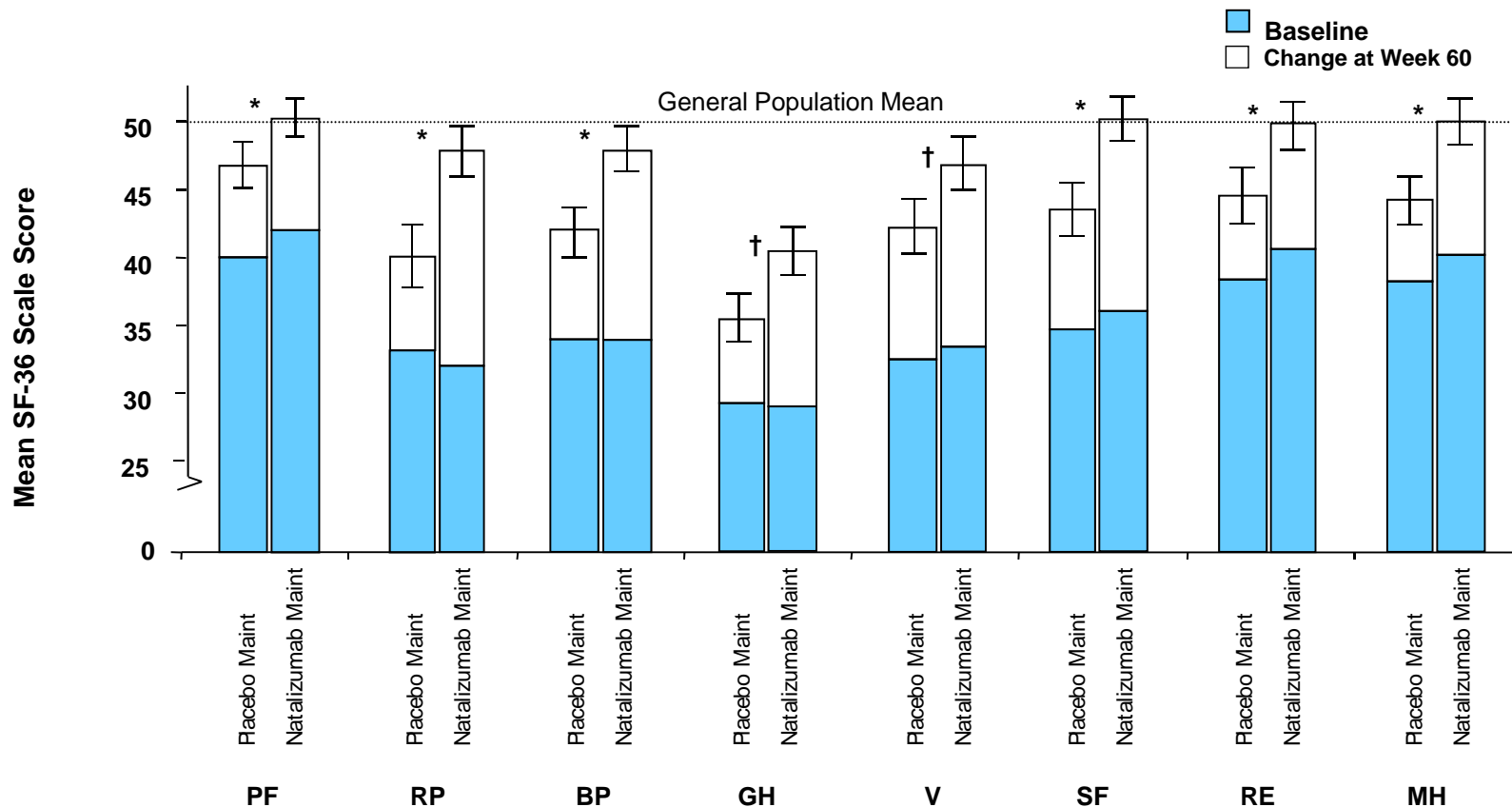
Study duration too short for endpoint (e.g., 6 weeks for DM meds)

Confounding effect (e.g. other medications might impact the outcome)

Lack of transparency

Anthem.

Evaluation of Quality of Life Data: SF-36 Results in Crohn's Disease



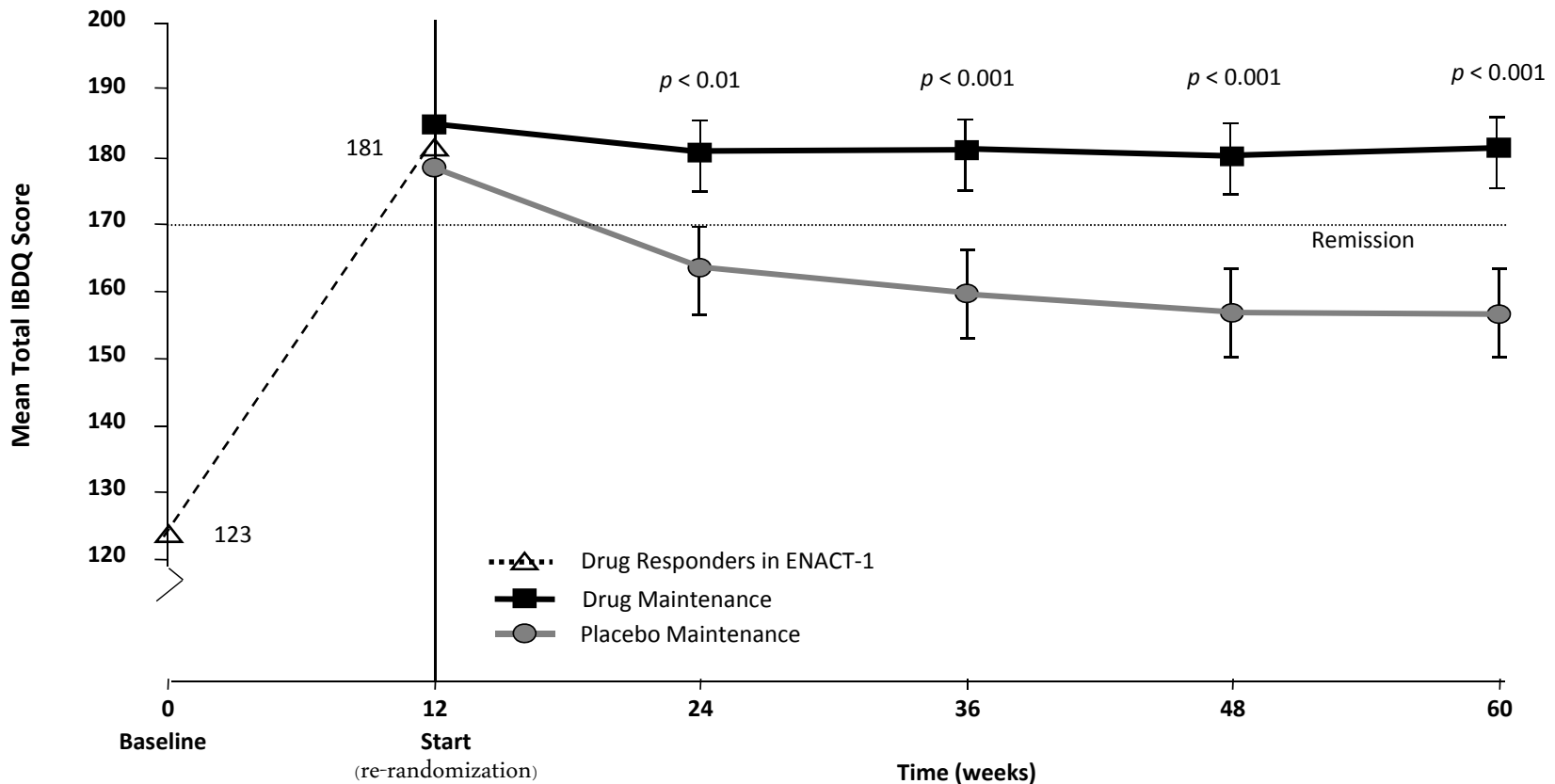
* - Significantly different from placebo; not significantly different from general population mean

† - Significantly different from placebo, and significantly different from general population mean

Physical Functioning = PF, Role-Physical = RP, Bodily Pain = BP, General Health = GH, Vitality = V, Social Functioning = SF, Role-Emotional = RE, Mental Health = MH

Feagan BG, Sandborn WJ, Hass S, Niecko T, White TJ. Health Related Quality of Life During Natalizumab Maintenance Therapy for Crohn's Disease. Am J Gastroenterol 2007;102:2737-2746.

IBDQ Results for Crohn's Disease Treatment



Percent of Patients Achieving ≥ 170 Threshold by Study Arm by Time Point

Placebo	65.9	46.9	43.9	40.9	40.0
Drug	79.5	73.0	72.6	68.1	71.3

QoL Summary

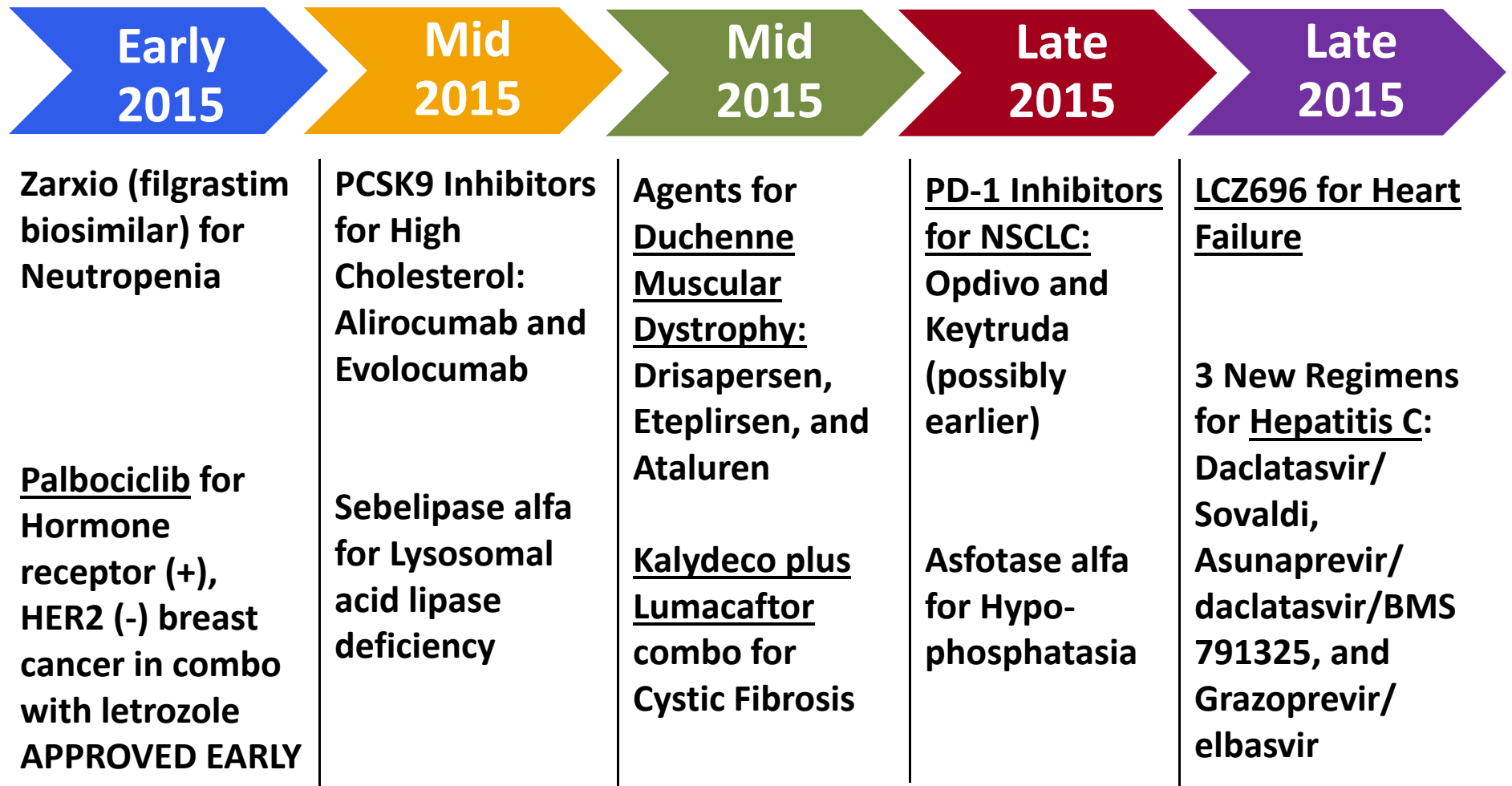
Some diseases are associated with significant QoL burden

Some treatments can result in significant improvement in QoL

- QoL consistent with disease in remission
- QoL approaches that of the US population norm

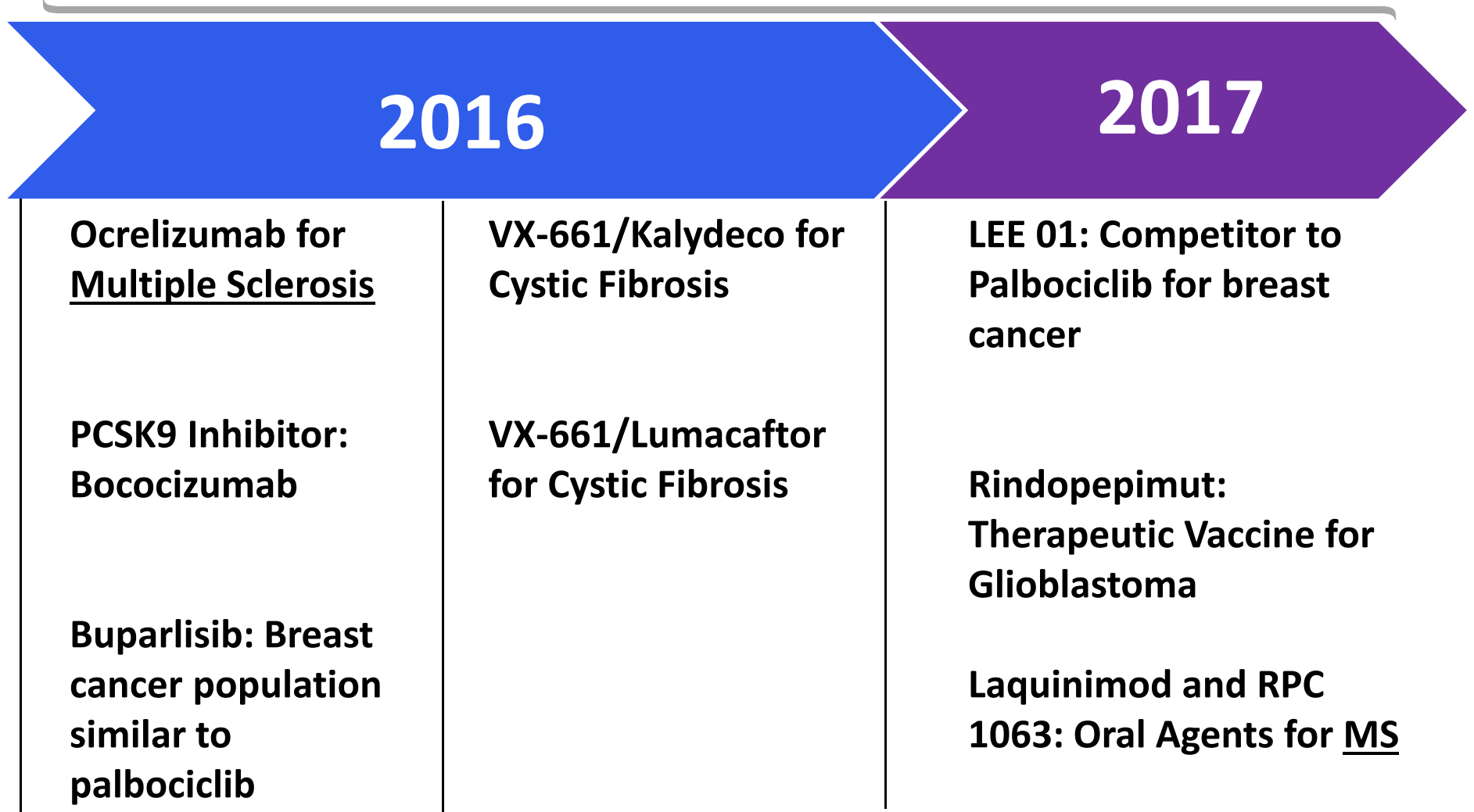
QoL is an important endpoint from a patient perspective

Future PRO Opportunity: Key Pipeline Drugs (1)



Note: Costs for drugs not approved are estimated.

Future PRO Opportunity: Key Pipeline Drugs (2)



Note: All costs for drugs not approved are estimated.

Summary

High quality evidence is important for health care decision-making

Some diseases are associated with significant QoL burden.

Treatment might result in significant improvement in QoL.

- QoL consistent with disease in remission
- QoL approaches that of the US population norm

QoL is an important endpoint from a patient perspective.

There are future opportunities for PROs to assist in health care decision-making.
